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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	ACS-53498 (21061)
First Inventor or Application Identifier	Brent Belding
Title	DETACHABLE SHEATH...
Express Mail Label No.	EL590182299US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
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Washington, DC 20231

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)*
(Submit an original and a duplicate for fee processing)

2. [X] Specification [Total Pages 42]
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. [X] Drawing(s) *(35 U.S.C. 113)* [Total Sheets 9]

4. Oath or Declaration [Total Pages 51]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

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5. [ ] Microfiche Computer Program *(Appendix)*

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   a. [ ] Computer Readable Copy
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ACCOMPANYING APPLICATION PARTS

7. [X] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503) (two) *(Should be specifically itemized)*
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APPLICATION

of

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for

UNITED STATES LETTERS PATENT

on

DETACHABLE SHEATH TO PROVIDE PRE-DEPLOYMENT STENT SECURITY AND ENHANCED DELIVERY PRECISION

Docket No. ACS-53498 (21061)

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DETACHABLE SHEATH TO PROVIDE PRE-DEPLOYMENT STENT SECURITY AND ENHANCED DELIVERY PRECISION

BACKGROUND OF THE INVENTION

This invention relates to apparatus and methods for the treatment of body lumens, and particularly to delivery systems for endoprostheses. More particularly, the invention relates to retaining devices for removably securing stents to catheters during delivery through human vasculature. The present invention also is directed to a delivery system for self-expanding stents which facilitates minimal stent movement during deployment to achieve more accurate stent placement within the patient's vasculature.

Several interventional treatment modalities are presently used for heart disease including balloon and laser angioplasty, atherectomy and by-pass surgery. In a typical cardiovascular intervention, a guiding catheter having a preformed distal tip is percutaneously introduced over a 0.035" wire that has been placed in the vasculature through a guiding sheath into an artery and advanced within the cardiovascular system until the distal tip of the guiding catheter is seated in the ostium of a coronary artery. The 0.035" wire is removed and a 0.014" guidewire is advanced distal to the treatment area. Then a dilatation catheter is back-loaded onto the 0.014" guidewire and tracked to the treatment area through the guiding catheter. Once in position across the lesion, the balloon is inflated to a predetermined size with radiopaque liquid at relatively high pressure (e.g., greater than four atmospheres) to compress the plaque of the lesion and to otherwise expand the inner lumen of the artery.

Further details of dilatation catheters, guidewires, and devices associated therewith for angioplasty procedures have been known for a number of years, and by way of example, several forms of such devices can be found in U.S. Patent No. 4,323,071 (Simpson-Robert); U.S. Patent No. 4,439,185 (Lindquist); U.S.

[1]Patent No. 4,516,972 (Samson); U.S. Patent No. 4,538,622 (Samson, et al.); U.S. Patent No. 4,554,929 (Samson, et al.); U.S. Patent No. 4,616,652 (Simpson); U.S. Patent No. 4,638,805 (Powell); U.S. Patent No. 4,748,982 (Horzewski, et al.); U.S. Patent No. 5,507,768 (Lau, et al.); U.S. Patent No. 5,514,154 (Lau, et al.); U.S. Patent No. 5,451,233 (Yock); and U.S. Patent No. 5,458,615 (Klemm, et al.); U.S. Patent No. 5,700,286 (Tartaglia, et al.).

A focus of recent development work in the treatment of heart disease has been directed to endoprosthetic devices called stents. Stents are generally cylindrically shaped intravascular devices which are placed within an artery to hold it open. The device can be used to reduce the likelihood of restenosis and to maintain the patency of a blood vessel immediately after intravascular treatments. In some circumstances, they can also be used as the primary treatment device where they are expanded to dilate a stenosis and then left in place.

Prior art stents typically fall into two general categories of construction. The first type of stent is expandable upon application of the controlled force, often through the inflation of the balloon portion of a dilatation catheter which, upon inflation of the balloon or other expansion means, expands the compressed stent to a larger diameter to be left in place within the artery at the target site. The second type of stent is a self-expanding stent formed from shape-memory metals or super-elastic nickel titanium (NiTi) alloys which will automatically expand from a compressed state when the stent is advanced out of the distal end of the delivery catheter into the body lumen. Such stents manufactured from expandable heat-sensitive materials allow for phase transformation of the materials to occur, resulting in the expansion and contraction of the stents.

One method and system developed for delivering stents to desired locations within the patient's body lumen involves advancing the stent delivery system through the patient's vascular system until the stent is positioned within the treatment area, and then inflating the expandable member on the catheter to expand the stent

within the blood vessel. The expandable member is then deflated and the catheter withdrawn, leaving the expanded stent within the blood vessel, holding open the passageway thereof.

However, retaining the position of the stent in the proper location on the expandable member while advancing the catheter through the body lumen can be compromised by tortuous vessels, calcified arteries, or previously placed stents. If the stent is dislodged from or moved relative to the expandable member, then the system will not correctly deliver the stent into the body lumen. This may require retrieval of the stent, repeat of the procedure, or surgery. All of these possibilities may adversely affect the patient's health.

Since the catheter and stent will be traveling through the patient's vasculature, and possibly through the coronary arteries, the stent must have a small delivery diameter and must be firmly attached to the catheter until the physician is ready to implant it. Thus, the stent must be loaded onto the catheter so that it does not interfere with delivery, and it must not come off of the catheter until it is implanted in the artery.

Different methods have been attempted to maintain the position of the stent on the expandable member. One such method involves a protective sheath surrounding the catheter and stent assembly, the sheath being retracted prior to inflation of the expandable member. The use of the sheath, however, increases the profile of the catheter assembly which must traverse stenosed and diseased vessels. In addition, the sheath increases the complexity of delivering the stent by requiring the physician to withdraw the sheath prior to inflation of the expandable member. It would be an improvement to use a technique which does not substantially increase the overall profile of the catheter assembly and does not require further manipulation by the physician.

There can be some additional problems associated when implanting self-expanding stents within the patient's vasculature. Some prior art stent delivery

systems for self-expanding stents including an inner lumen upon which the compressed or collapsed stent is mounted and an outer restraining sheath which is eventually placed over the compressed stent prior to deployment. When the stent is to be deployed in the body vessel, the outer sheath is moved in relation to the inner lumen to "uncover" the compressed stent, allowing the stent to move to its expanded condition. Some delivery systems utilize a "push-pull" technique in which the outer sheath is retractable while the inner sheath is pushed forward. Still other systems use an actuating wire which is attached to the outer sheath. When the actuating wire is pulled to retract the outer sheath over the collapsed stent, the inner lumen must remain stationary, preventing the stent from moving axially within the body vessel.

There have been problems associated with the prior art delivery systems for self-expanding stents. For example, systems which rely on a "push-pull" design can experience movement of the compressed stent within the body vessel when the inner lumen is pushed forward which can lead to inaccurate positioning and, in some cases, possible perforation of the vessel wall by a protruding end of the stent. Systems which utilize the actuating wire design tend to follow the radius of curvature when placed in the curved anatomy of a patient. As the wire is actuated, tension and delivery systems can cause the wire to straighten. As the system straightens, the position of the stent changes because of the length of the catheter no longer conforms to the curvature of the anatomy. This changes the geometry of the system within the anatomy and can also lead to inaccurate stent positioning.

Since proper positioning of the stent is critical to the performance of the stent, it is imperative that the physician knows exactly where the stent will be placed upon deployment. Some existing self-expanding stents can store energy axially as the outer restraining sheath is retracted. Frictional force generated as the outer sheath is retracted over the compressed stent can cause the stent to act somewhat like a spring, storing energy as the frictional forces act on the stent. This stored energy can be released as the stent expands beyond the end of the sheath, causing the

stent to move or "jump" from the catheter away from the desired position, resulting in inaccurate stent placement. The amount of energy stored is dependent on the flexibility of the stent and the friction between the stent and outer sheath.

What has been needed and heretofore unavailable is a satisfactory retaining device for maintaining an endoprosthesis in a desired location on a delivery catheter without significantly increasing the overall profile of the catheter assembly, without requiring manipulation of the retaining device by the physician and without requiring the retaining device to expand with an expandable member of the catheter assembly. This device is also intended to give the user 100% confidence that the stent will not be dislodged prior to placement and deployment in the treatment segment. There is also a need for a stent delivery system that facilitates minimal movement during deployment of a self-expanding stent to provide for more accurate stent placement. Such a delivery system should help prevent the self-expanding stent from "jumping" from the delivery system to allow for more accurate positioning within the body lumen. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention is directed to a catheter assembly for delivering an endoprosthesis within a body lumen. More particularly, the invention relates to a delivery catheter assembly including a detachable sheath for removably securing an endoprosthesis onto an expandable member (for example, a balloon). The detachable sheath is associated with a catheter assembly having an expandable member therein, whereby inflation of the expandable member ruptures the detachable sheath, thereby exposing the endoprosthesis for implantation into a body lumen. Alternatively, the detachable sheath may be inflated separately from the expandable member, and may be manually retracted from the

endoprosthesis. The detachable sheath prevents movement of the endoprosthesis relative to the catheter assembly during deployment in a body lumen, such as a patient's vasculature, by covering the endoprosthesis until the endoprosthesis is positioned at the desired location within the body lumen. The retaining device of the present invention can be used with the common configurations of delivery catheter assemblies, including over-the-wire intravascular catheters, rapid exchange intravascular catheters, monorail intravascular catheters, and perfusion-type catheters.

In one embodiment of the invention, the detachable sheath is configured to removably secure a stent to a delivery catheter assembly. Such a catheter assembly includes a catheter tube, wherein a balloon is formed on the distal end portion of the catheter tube and a stent is disposed on the balloon. A sheath is secured to the distal end portion of the catheter tube, such that the sheath is stretched over the balloon and over the stent. The sheath includes a weakened section configured to rupture during inflation of the balloon. In addition, the sheath may include a plurality of circumferential perforations to enhance rupture of the sheath at a desired location. In an alternative embodiment of the catheter assembly, the proximal end portion of the sheath is positioned proximal to the proximal end portion of the catheter tube, and the distal end portion of the sheath is configured with a weakened section and secured to the distal end portion of the catheter tube. Such a detachable sheath may further include an inflation port positioned proximate the proximal end portion of the sheath. The proximal end portion of such a sheath may be secured to the proximal end portion of the catheter tube, wherein the sheath is stretched prior to securing the sheath to the catheter tube.

The invention results in a simplified method of delivering an endoprosthesis -- for example, a stent -- into a body lumen -- for example, a human vasculature. A delivery catheter assembly is provided that includes a catheter assembly having an expandable member associated with the distal end portion of the catheter. An endoprosthesis is disposed on the expandable member, and a detachable

sheath is disposed on the catheter and over the endoprosthesis, wherein the sheath is configured to rupture during expansion of the expandable member. The catheter assembly is inserted into the vasculature and manipulated so that the distal end of the catheter tube is positioned proximal to a desired location in the vasculature, such as at a lesion or stenosis in a coronary artery. The detachable sheath firmly holds the stent onto the expandable member while traversing the vasculature. The expandable member (in some configurations, a dilatation balloon) is inflated at the desired location in the vasculature, thereby rupturing the sheath and exposing the stent. Alternatively, the sheath may be separately inflated from the expandable member, and/or may be retracted manually. The expandable member is further inflated, thereby expanding and implanting the stent at the desired location. The expandable member is then deflated, the stent is released and the remainder of the catheter assembly, including the ruptured sheath is withdrawn, leaving the stent permanently implanted within the vasculature.

The prosthesis could be, for example, a self-expanding stent which would expand once the detachable sheath has been ruptured by the expansion of the expandable member. In this fashion, the self-expanding stent starts to deploy as soon as the sheath ruptures allowing the stent to be deployed within the patient's vasculature. The structure of the detachable sheath and catheter would be substantially the same for a self-expanding stent as it would be for the balloon expandable stent, except that the sheath may have to resist the forces exerted by the self-expanding stent as it remains in its collapsed position until the stent is ready to be deployed. For this reason, the detachable sheath may have to be made from a suitably stronger material to maintain the self-expanding stent in its collapsed position until the expandable member is expanded to rupture the sheath. A delivery catheter assembly made in accordance with the present invention for use in deploying a self-expanding stent should help prevent the stent from "jumping" from the catheter

during deployment to allow for more accurate placement within the patient's vasculature.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts a longitudinal plan view of an embodiment of a catheter assembly including a detachable sheath of the present invention.

FIG. 2 depicts a cross-sectional view along lines 2-2 of FIG. 1.

FIG. 3 depicts a partial longitudinal plan view of a distal portion of a catheter assembly including a detachable sheath of the present invention, including a hidden view of a stent mounted on a balloon.

FIG. 4 depicts a partial longitudinal plan view of the catheter assembly of FIG. 3, wherein the detachable sheath has been ruptured, thereby exposing the stent and the balloon.

FIG. 5 depicts a partial longitudinal plan view of the catheter assembly of FIG. 3, wherein the detachable sheath has retracted longitudinally, fully exposing the stent and the balloon.

FIG. 6 depicts a partial longitudinal plan view of the catheter assembly of FIG. 3, wherein the detachable sheath has been ruptured as a result of the balloon

expanding first at the proximal and distal edges, thereby exposing the stent and the balloon.

FIG. 7A depicts a longitudinal plan view in partial cross-section of an intravascular catheter assembly including an alternative embodiment of a detachable sheath of the present the invention, wherein the detachable sheath extends from proximate the proximal end of the catheter assembly.

FIG. 7B depicts a partial longitudinal plan view of a distal portion of the catheter assembly of FIG. 7A.

FIG. 8 depicts a longitudinal plan view in partial cross-section of an over-the-wire intravascular catheter assembly including a detachable sheath of the present the invention.

FIG. 9 depicts a longitudinal plan view in partial cross-section of a rapid exchange intravascular catheter assembly including a detachable sheath of the present the invention.

FIG. 10 depicts a longitudinal plan view of a stent delivery catheter assembly, including a detachable sheath of the present invention, wherein a stent is shown in a hidden view.

FIG. 11 depicts a longitudinal plan view of a stent delivery catheter assembly, including a detachable sheath of the present invention, partially inserted within the cross-section of a patient's vessel, wherein a stent is shown in a hidden view.

FIG. 12 depicts a longitudinal plan view of a stent delivery catheter assembly, including a detachable sheath of the present invention, which has been positioned proximate a dissected lining within a cross-section of a patient's vessel, wherein a stent is shown in a hidden view.

FIG. 13 depicts a longitudinal plan view of a stent delivery catheter assembly, including a detachable sheath of the present invention, which has been positioned proximate a dissected lining within a cross-section of a patient's vessel, wherein the sheath has ruptured and begun to retract longitudinally.

FIG. 14 depicts a longitudinal plan view of a stent delivery catheter assembly, including a detachable sheath of the present invention, which has been positioned proximate a dissected lining within a cross-section of a patient's vessel, wherein the sheath has fully retracted longitudinally and the balloon and stent are fully expanded.

FIG. 15 depicts a longitudinal plan view depicting a partially withdrawn stent delivery catheter assembly, including a detachable sheath of the present invention, wherein a stent has been deployed within a cross-section of a patient's vessel.

FIG. 16 depicts a longitudinal plan view of a catheter assembly including detachable sheath made in accordance with the present invention wherein the detachable sheath has been ruptured, thereby exposing a self-expanding stent which is mounted on the balloon portion of the catheter.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the present invention is directed to a delivery catheter assembly including a detachable sheath for removably securing an endoprosthesis -- for example, a stent -- onto an expandable member -- for example, a balloon -- associated with the distal end portion of the catheter assembly. The improved catheter assembly overcomes many of the problems associated with prior delivery catheters regarding securing the endoprosthesis to the expandable member of the catheter. The detachable sheath of the present invention reliably and inexpensively secures the endoprosthesis to the expandable member while traversing the patient anatomy, yet provides for safe and easy deployment of the endoprosthesis at the target site in a body lumen.

A focus of recent development work in the treatment of heart disease has been directed to endoprosthetic devices called stents. One method and system developed for delivering stents to desired locations within the patient's body lumen involves crimping a stent about an expandable member, such as a dilatation balloon on the distal end of a catheter, advancing the catheter through the patient's vascular system until the stent is in the desired location within a blood vessel, and then inflating the expandable member on the catheter to expand the stent within the blood vessel. However, retaining the stent in the proper location on the expandable member while advancing the catheter through the patient vasculature has been found to be difficult. The improved catheter assembly having a detachable sheath of the present invention solves this stent slippage problem.

While the invention is described in detail as applied to the use of catheter assembly having a detachable sheath for positioning a stent in the coronary arteries, those skilled in the art will appreciate that the improved catheter assembly can be applied to a variety of endoprostheses for use in other body lumens and patient vasculature, such as, but not limited to, peripheral arteries and veins. Although the

invention is described with respect to covering a stent on the balloon portion of a catheter, the invention is not so limited and includes protecting stents, grafts or other endoprostheses on any type of catheter used to deliver and implant such devices.

With reference to the drawing figures, where different embodiments incorporating the invention have like elements, like reference numbers have been used.

Referring now to the drawings and more particularly to FIGS. 1 and 2, there is shown a distal portion of an embodiment of a catheter assembly 20 incorporating the features of the present invention. The catheter assembly includes an inner elongate tubular member 22 configured to encompass a guidewire 24 positioned to slide within an inner lumen of the elongate tubular member. A catheter tube 30 is disposed on and preferably secured to the elongate tubular member. The catheter tube includes an expandable member 31, for example a dilatation balloon, formed on or secured to its distal portion. The catheter tube further has a proximal portion 32, which may extend the length of the catheter assembly, culminating in a proximal portion of the catheter assembly, for example a sidearm (not shown), which may include an inflation port in fluid communication with the catheter tube, and may include a guidewire port in communication with a proximal end of the inner elongate tubular member. In addition, the catheter tube has a distal end 34 which is glued, bonded, heat shrunk or otherwise secured to and proximate of a distal end 23 of the elongate tubular member.

The expandable member or balloon 31 is formed just proximal of the distal end 34 of the catheter tube 30. Alternatively, the balloon can be a separate element of the catheter assembly, which is secured to and in fluid communication with a lumen in the proximal portion of the catheter tube 32. In such a configuration, the elongate tubular member 22 is not a necessary element of the catheter assembly, and the guidewire 24 may be disposed within a separate lumen of the catheter tube.

The distal portion of the catheter assembly 20 further includes an endoprosthesis 50, such as a stent, crimped or otherwise disposed on the catheter tube 30. The stent is positioned between the distal end 34 and the proximal portion 32 of the catheter tube, particularly on the expandable member 31. As shown in FIG. 2, the non-solid, lattice nature of many of the present day stent configurations may result in a non-uniform application of the stent elements on the balloon. Furthermore, to reduce the overall profile of the catheter assembly, the expandable member may be folded such that the cross-section of the expandable member is not circular in nature. In many stent delivery catheters, the expandable member is a dilatation balloon having been arranged in a multiple-fold or no-fold configuration prior to positioning the stent on the balloon.

The improvement of the catheter assembly over the prior art is the addition of a detachable sheath 40 on the distal portion of the catheter assembly 20. The sheath is disposed over the endoprosthesis (stent) 50, and is also disposed over the expandable member (balloon) 31 of the catheter tube 30. An advantage of the detachable sheath is that it envelopes the endoprosthesis, preventing the endoprosthesis from contacting the patient's vasculature and from becoming dislodged from its position on the expandable member.

The detachable sheath 40 has a proximal end 42, which may be glued, bonded, heat shrunk or otherwise secured to the proximal portion 32 of the catheter tube 30 just proximal of the expandable member 31. Further, the sheath has a distal end 44 which may be glued, bonded, heat shrunk or otherwise secured to the distal end 34 of the catheter tube and/or to the distal end 23 of the elongate tubular member 22. Alternatively, the proximal end of the detachable sheath may extend to and may be secured proximate the very proximal end of the catheter tube (FIG. 7A). In such a case, the sheath may be inflated separately of the expandable member.

Referring to FIGS. 3-6, the detachable sheath 40 is configured to rupture upon expansion of the expandable member 31 of the catheter tube 30. For

example, the sheath may be configured to rupture at an inflation pressure of two atmospheres; whereas, the nominal inflation of the expandable member is eight atmospheres. To aid in the rupture at a specific portion of the sheath, the sheath may be scored or provided with one or more (a plurality) of perforations 46. The scoring or perforations may be placed at specific location of the sheath, for example, circumferential about the midline, to provide a specific detachment of the sheath into two halves (FIG. 3). Moreover, the sheath may be stretched over the stent 50 and catheter tube 30 prior to securing the sheath to the catheter, such that one of the broken halves of the sheath will retract towards the proximal portion 32 of the catheter tube, and the other broken halve will retract towards the distal end 34 of the catheter tube. This automatic retraction of the detachable sheath has the advantage over prior art sheaths that it does not require manipulation by the physician to displace the sheath from surrounding the stent.

The scoring or perforations 46 in the sheath 40 may be made by any process known to those skilled in the art, such as with a sharp knife or razorblade, a laser, etc. The scoring and perforations, however, are not necessary features of the detachable sheath. Alternatively, the sheath may be weakened at a location where the sheath is desired to rupture. The sheath may be weakened by softening the desired area with heat, or otherwise deforming the micro-structure of the sheath material at the desired location.

It should be appreciated to those skilled in the art that the location where the sheath is to rupture need not necessarily occur about the midline, as is shown in the Figures, to provide detachment of the sheath into two substantially equal halves. Rather, the scoring, preparations or weakening of the sheath can take place at other locations along the sheath without departing from the spirit and scope of the present invention.

As shown in FIG. 4, introduction of inflation fluid (air, saline, etc.) 38 into the catheter tube 30 causes the expandable member 31 to expand in an outwardly

(transverse) direction 56. The expansion of the expandable member causes the detachable sheath 40 to rupture, preferably creating two halves having edges 48, which is facilitated by the scoring of perforations 46 in the sheath. The expansion of the expandable member causes the edges of the sheath to move in a longitudinal direction 54 towards the proximal end 42 and the distal end 44 of the sheath, and towards the proximal portion 32 and distal end 34 of the catheter tube. As the expandable member expands and the sheath retracts, the stent 50 becomes exposed to the body lumen. Once the balloon is fully expanded, the stent also becomes fully expanded (FIG. 5). So as to not interfere with implantation of the stent, the broken portions of the sheath should retract towards the proximal and distal ends of the catheter tube sufficiently to fully expose the stent. Such longitudinal movement is facilitated by the initial stretching of the sheath over the stent and the balloon.

In many configurations of stent delivery catheter assemblies having a catheter tube 30, the proximal and distal portions of the expandable member 31 will expand first and to a greater degree than the middle portion of the expandable member, which is restrained somewhat by the stent 50. As shown in FIG. 6, the expandable member expands first at the proximal and distal edges. Expansion of the ends of the expandable member creates a longitudinal force 54 on the sheath 40, causing the sheath to rupture and the edges 48 to retract prior to any significant radial expansion 56 of the stent and middle portion of the expandable member.

In an alternative embodiment of the stent delivery catheter 90 as shown in FIGS. 7A and 7B, a longer sheath 40 is provided such that the proximal end 42 of the sheath is positioned outside of the patient and somewhat distal of the proximal portion (sidearm) 91 of the delivery catheter assembly. As before, the distal end 44 of the sheath is positioned just proximal of the distal end 92 of the catheter assembly. The catheter proximal portion (sidearm) includes a guidewire port 94 for receiving a proximal end 25 of a guidewire 24, and includes an inflation port 96 for introducing inflation fluid into the catheter tube 30 and the expandable member (balloon) 31. The

sheath proximal end is secured to the proximal portion 32 of the catheter tube somewhat distal of the guidewire port and the balloon inflation port (sidearm). The proximal portion of the sheath is configured with an inflation port 100 positioned somewhat distal of the point of attachment of the sheath to the catheter tube. The inflation port may include a Luer lock or any other appropriate fitting for inflating the dedicated lumen with any inflation device. Another option is to mold an extension onto the sheath during its manufacture. The extension could be connected to a syringe or indeflator for inflation. Alternatively, the sheath could be made so that it does not have to be sealed to the catheter at the proximal attachment site, but rather has an open flap at that location. The flap could be clamped with a hemostat and the sheath inflated through a fitting attached to the sheath. When the distal end of the sheath detaches from the catheter due to the inflation, the physician could use the hemostat to retract the sheath proximally.

As shown in FIG. 7B, the sheath distal end 44 is secured to the distal end 34 of the catheter tube 30 and/or to the distal end 23 of the elongate tubular member 22, in which the guidewire 24 is disposed. The sheath distal end is scored, perforated or otherwise weakened as described heretofore to permit the sheath distal end to break away from the catheter tube and elongate tubular member when inflation fluid 98 is introduced into the sheath 40. The perforations could be made in any other location that would allow pullback and/or detachment of the sheath. If the sheath can be stretched tightly enough, then there may be no need to perforate it and seal it. Rather, if the clearance between the inner surface of the sheath and the outer surface of the outer member is small enough, then fluid injected into the sheath inflation lumen could inflate the sheath while the fluid leaking out could provide the lubrication required to retract the sheath. Alternatively, a perforation could run the longitudinal length of the sheath with or without the need for distal perforation and seal.

The sheath 40 can be separately inflated at low pressure by introducing inflation fluid 98 into the sheath inflation port 100 until the sheath distal end 44 tears away and disengages from the distal end 34 of the catheter tube 30 and exposes the stent 50. Once inflated and detached, the sheath could be manually retracted toward the proximal end 91 of the stent delivery catheter in order to expose the stent. Pre-stretching the sheath over the catheter tube and the stent provides for automatic retraction of the sheath from the expandable member 31 and from the stent. The sheath can be further retracted by pulling on the proximal end 42 of the sheath by the physician. After the sheath is retracted from the expandable member and the stent, the expandable member can be separately inflated to its nominal pressure to deploy the stent. This alternative embodiment differs from the embodiment discussed herein regarding FIGS. 1-6 wherein the sheath and expandable member expand simultaneously when the expandable member is inflated. This alternative embodiment of the sheath is best-suited to an over-the-wire system, as the sheath would interfere with using the exit notch of a rapid exchange system.

The alternative embodiment shown in FIGS. 7A & 7B allows the physician to advance the stent delivery system to the vicinity of the lesion and inflate/detach the sheath using the dedicated inflation lumen. Then, the physician can advance the stent into the lesion and deploy the stent. With the embodiment shown in FIGS. 1-6, the physician does not have this option since the sheath and stent inflate simultaneously. The second embodiment is potentially more deliverable than the first embodiment, since its profile can be reduced by removing the sheath prior to stent deployment. The longer sheath of the second embodiment could enhance its pushability due to the added bulk material. The inflation fluid could also be a drug (for instance collagenase) or any other substance that would be useful in treating a lesion prior to stent deployment. The device would not be used primarily for drug delivery, but rather the inflation fluid would leak out of the sheath as a consequence

of deployment. The sheath could be coated or surface-treated to enhance manual proximal retraction over the stent and catheter.

The detachable sheath 40 is made from a suitable biocompatible material, for example, polymers and composites. Suitable non-stretchable materials include, but are not limited to, polyethylenes, polyethylene terephthalate (PET), polyamides such as nylon, polyesters and polytetrafluoroethylene (PTFE). If the sheath is to be stretched over the stent and expandable member, the sheath should be configured to have a durometer shore hardness of about 45D or below, and capable of elongation of at least three hundred percent. Suitable stretchable or elastomeric materials include, but are not limited to, aromatic and aliphatic polyurethanes, poly-etheretherketone (PEEK), polyester amides such as Pebax, copolyesters such as Arnitel, Hytrel and Pelprene, and expandable polytetrafluoroethylene (e-PTFE). One suitable thermoplastic polymer is C-FLEX, which is a trademarked product available from Concept Polymer Technologies of Largo, Florida. A suitable polyurethane is TECOPHILIC, which is a trademarked product available from Thermedics, of Woburn, Mass. Furthermore, in case one or more portions of the sheath break off into the patient's vasculature, the retaining device may be made from a biodegradable material, such as, but not limited to, polylactic acid (PLA), poly-L-lactic acid (PLLA), polyglycolic acid (PGA), fibrin, elastin and collagen. Other suitable materials can be used as are known to those skilled in the art.

Where the sheath material causes the stent to unduly stick to the sheath, a lubricious coating may be applied to the inside of the sheath. Suitable lubricants include, but are not limited to polyethylene oxides, glycols and silicone based compounds. Suitable lubricants include MICROGLIDE and HYDROCOAT, trademarked products manufactured by Advanced Cardiovascular Systems, Inc. of Santa Clara, California. Alternatively, the inside or outside of the sheath could be plasma treated to allow attachment of functional groups and/or molecules which reduce or increase the friction between the sheath, stent and expandable member, as

well as the friction between the external layer of the sheath and any contact material. Other suitable lubricants can be used as are known to those skilled in the art.

One particularly suitable material that can be readily stretched and can be configured to rupture at about two atmospheres of inflation pressure is the polyurethane "ESTANE," a trademarked product available from BF Goodrich of Charlotte, North Carolina. The ESTANE sheath may be initially formed with an inner diameter of 0.032 inches (0.81 mm) and an outer diameter of 0.042 inches (1.07 mm). The ESTANE sheath may be expanded to an inner diameter of 0.038 inches (0.974 mm) and an outer diameter of 0.046 inches (1.18 mm), by heating at 250 °F (120 °C) over a TEFLON – polytetrafluoroethylene (PTFE) – sheath having an outer diameter of 0.05 inches (1.27 mm), using an air flow of twenty-five ft^3/hr (0.71 m^3/hr) and air pressure of eighty psi (5.5 atm). The expanded ESTANE tubing may then be scored with three equidistant slits along the circumference of the sheath, using a razorblade or similar sharp instrument. The proximal end of the sheath may then be secured the proximal portion of the expandable member using an adhesive, such as LOCTITE 3201, a trademarked product available from the Loctite Corporation. The sheath may then be pulled from two hundred to three hundred percent expansion elongation on the distal end. The distal end of the sheath may then may be laser sealed to the distal end of the expandable member or elongate tubular member.

A stent delivery catheter assembly including the detachable sheath of the present invention can be configured by modifying commonly known stent delivery systems. As shown in FIG. 8, the catheter assembly may be configured as an over-the-wire (OTW) intravascular catheter 60. The OTW catheter includes a proximal portion (sidearm) 61 and a distal portion 62. The proximal portion includes a guidewire port 64 for receiving a proximal end 25 of a guidewire 24. The OTW catheter proximal portion also includes an inflation port 66. An inner elongate tubular member 22 extends from the OTW catheter proximal portion (sidearm) to the OTW catheter distal end, and is configured with a lumen for slidably receiving the guide-

wire. A catheter tube 30 is disposed over the elongate tubular member, and has a proximal portion 32 which extends from the sidearm to an expandable member 31 at the distal section of the catheter tube. The catheter tube is configured with an inflation lumen 36 in fluid communication with the inflation port. The catheter tube further has a distal end 34 secured to the distal end 23 of the elongate tubular member. A stent 50 is disposed on an expandable member 31 of the catheter tube, configured proximate the distal end of the catheter tube and the distal end of the elongate tubular member. A detachable sheath 40 is disposed over the stent and expandable member, and is secured to the distal portion of the OTW catheter. As will be appreciated by those of ordinary skill in the art, various forms of OTW catheters may be employed without deviating from the scope of the invention.

As shown in FIG. 9, the catheter assembly may be configured as a rapid exchange (Rx) intravascular catheter 70. The Rx catheter includes a proximal portion 71 and a distal portion 72. The Rx catheter proximal portion includes an inflation port 76 in fluid communication with a rigid member (hypotube) 78 connected to and in fluid communication with a proximal portion 32 of a catheter tube 30, having an inflation lumen 36. The catheter tube further has a distal end 34 secured to a distal end 23 of an elongate tubular member 22 within which is disposed a guidewire 24. The guidewire exits a distal end 74 of the elongate tubular member proximate the distal portion of the catheter tube. A stent 50 is disposed on an expandable member 31 of the catheter tube, configured proximate the distal end of the catheter tube and the distal end of the elongate tubular member. A detachable sheath 40 is disposed over the stent and expandable member, and is secured to the distal portion of the Rx catheter. As will be appreciated by those of ordinary skill in the art, various forms of Rx catheters may be employed without deviating from the scope of the invention.

As discussed above, the delivery catheter assembly 20, as described herein, can have an over-the-wire (OTW) or rapid exchange (Rx) configuration as more fully disclosed in, but not limited to, U.S. Patent No. 4,323,071 (Simpson et al.)

(OTW); U.S. Patent No. 4,573,470 (Samson et al.) (OTW); U.S. Patent No. 5,501,227 (Yock) (Rx); U.S. Patent No. 5,061,273 (Yock) (Rx); and U.S. Patent No. 5,496,346 (Horzewski et al.) (Rx). Likewise, the stent 50, as described herein, can have various configurations, and suitable stents include, but are not limited to, the ACS MULTI-LINK STENT sold by Advanced Cardiovascular Systems, Inc., Santa Clara, California; the NIR STENT sold by Boston Scientific, Natick, Massachusetts; and the MICRO STENT II and GFX sold by Arterial Vascular Engineering, Santa Rosa, California. The ACS MULTI-LINK STENT mounted on a rapid exchange delivery catheter is disclosed in U.S. Patent No. 5,514,154 (Lau et al.).

When combined with a stent delivery catheter assembly, a detachable sheath of the present invention results in an improved process for delivering and implanting a stent to a desired location within a patient's vasculature. Figures 10 through 15 illustrate, by way of example, a method of delivering and implanting a stent 50 mounted on a balloon 31 of a catheter tube 30, including an embodiment of the detachable sheath 40. While the drawing figures illustrate a rapid exchange (Rx) intravascular catheter 20, embodiments of the retaining device may also be used with an over-the-wire (OTW) intravascular catheter.

The figures illustrate a situation in which the stent delivery catheter having a detachable sheath is used to support a dissected arterial lining to prevent the dissection from collapsing into the arterial passageway and impeding sufficient blood flow through the vessel. In addition, the stent delivery catheter having a detachable sheath may be used in a balloon angioplasty procedure in which a stent is used to support the vasculature to prevent restenosis. Furthermore, the procedures and devices described herein may be adapted by one of ordinary skill in the art to any procedure where a endoprosthesis is to be placed into a body lumen.

As shown in FIG. 10, a catheter assembly 20 is provided with detachable sheath 40 covering a stent 50 removably secured on an expandable member 31 formed on or secured to a catheter tube 30. The detachable sheath is

secured to the catheter, as heretofore described. Referring to FIG. 11, the catheter assembly is inserted into the lumen of vessel of a patient's vasculature 80, such as a coronary artery, along a guidewire 24 having a distal end 26, which is previously positioned distal to the desired location 84 requiring support. The expandable member, including the stent covered by the detachable sheath, is then moved in a distal direction until the detachable sheath and stent are positioned proximate a dissected lining 82 at the desired location in the patient's vasculature (FIG. 12).

As illustrated in FIG. 13, once the stent 50 is positioned at the desired location 84 of the vessel 80, the expandable member (balloon) 31 of the catheter tube 30 is inflated. This may be accomplished, for example, by injecting inflation fluid under substantial pressure into a lumen of the catheter tube. Once a first pressure is realized, which is less than the nominal inflation pressure of the balloon, the detachable sheath 40 ruptures. As the detachable sheath ruptures, the broken edges 48 of the detachable sheath retract longitudinally, thereby partially exposing the stent. As the balloon continues to expand to its nominal (second) pressure, the ruptured detachable sheath fully retracts away from the stent. Simultaneously, the stent continues to expand, until it is fully expanded and implanted in the vessel (FIG. 14). After the stent is fully expanded, the balloon is then deflated or otherwise contracted; however, the expandable stent remains implanted at the desired location in the vessel. Once the stent is no longer in contact with the catheter assembly, then the catheter tube, balloon, ruptured detachable sheath, and guidewire 24 are withdrawn from the vasculature (FIG. 13).

Referring now to FIG. 16, a self-expanding stent 110 is shown positioned on a catheter assembly which is similar to the one shown in FIGS. 3-6. Therefore, like members have been designated with the same reference numerals in FIG. 16. As can be seen in FIG. 16, the detachable sheath 40 has a proximal end 42 which may be glued, heat bonded, heat shrunk or otherwise secured to the proximal portion 32 of the catheter tube 30 just proximal of the expandable member 31.

Likewise, the sheath 40 has a distal end 44 which may be glued, heat bonded, heat shrunk or otherwise secured to the distal end 34 of the catheter tube or to the distal end 23 of the elongate tubular member 22. Alternatively, the proximal end of the detachable sheath may extend to and may be secured proximate to the very end of the catheter tube. In such a case, the sheath may be inflated separately from the expandable member.

The detachable sheath 40 shown in FIG. 16 is configured to rupture upon expansion of the expandable member 31 of the catheter tube 30. The detachable sheath 40 should be made from suitable material, such as the sheathing material described above, except that the sheath 40 may require additional strength to maintain the self-expanding stent 110 in its collapsed, unexpanded position while on the catheter. This is due to the outward radial force generated by the self-expanding stent on the sheath, which in this configuration would cause the stent to expand from the center outward. Therefore, the amount of force which must be developed by the expandable member 31 in order to rupture the detachable sheath 40 may be less than required to rupture a sheath which covers a balloon expandable stent since the force developed by the self-expanding stent 110 also assists in rupturing the sheath 40.

As can be seen in FIG. 16, the dynamics behind the expansion of the self-expanding stent 110 are a bit different than the dynamics when deploying a balloon expandable stent. As the inflatable member 31 is inflated to rupture the sheath 40, the expandable stent 110 immediately proceeds to expand radially outward from the center, as can be seen in FIG. 16. This is different from the configuration of the catheter as shown in FIG. 6 as the balloon expandable stent is being expanded by the expandable member 31. The dynamics in deploying a self-expanding stent 110 from the catheter assembly helps prevent the stent 110 from "jumping off" of the catheter as the sheath 40 is being ruptured by the inflatable member 31. As a result, the placement of the self-expanding stent 110 within the patient's vasculature should be quite accurate since the initial expansion of the extension of the central section of

the stent should help prevent the "jumping" phenomena from occurring during stent deployment.

Referring back to FIG. 16, as the sheath 40 is ruptured, the expandable member 31 does not need to be inflated further to deploy the self-expanding stent since the ruptured sheath 40 should immediately retract back towards its proximal end 42 and distal end 44, allowing the self-expanding stent 110 to fully deploy. However, it should be appreciated by one skilled in the art that the deflatable member 31 could be further inflated, if desired, to ensure that the self-expanding stent 110 is fully expanded into its deployed condition with the patient's vasculature.

The catheter assembly 20 with a self-expanding stent 110 could be similarly deployed in the patient's vasculature as is shown in the sequence depicted in FIGS. 11-15. The expandable member 31 of the catheter assembly 20 may have a limited role in deploying the self-expanding stent 110 within the patient's vasculature, in that the expandable member could be used only to rupture the detachable sheath to initiate the deployment of the self-expanding stent 110. Alternatively, the expandable member 31 could be continued to be inflated to ensure that the self-expanding stent 110 is fully deployed within the vasculature, as addressed above. After the self-expanding stent has been fully deployed within the vasculature, the catheter assembly 20, with its expandable member and ruptured sheath can be withdrawn, along with the guide wire, from the patient's vasculature.

It should be appreciated that the location of the perforations which are placed on the sheath 40 need not necessarily be located directly at the midline of the sheath 40, as is disclosed in FIG. 16. Rather, the perforations or scoring could be done at other locations along the sheath 40 without departing from the spirit and scope of the present invention.

The dimensions of the intravascular catheter will generally follow the dimensions of intravascular catheters used in angioplasty procedures in the same arterial location. Typically, the length of a catheter assembly for use in the coronary

arteries is about one hundred thirty-five to one hundred fifty centimeters, the outer diameter of the catheter expandable member is about one millimeter, the length of the balloon is typically about two centimeters and the inflated diameter of the balloon is about one to about five millimeters, depending upon the application. Catheter dimensions for peripheral use will vary, and is known in the art. The materials of construction of the catheter assembly, catheter tube and expandable member may be selected, for example, from those used in conventional balloon angioplasty catheters. Furthermore, the specific dimensions and materials of construction of the detachable sheath are provided as examples, and substitutes are readily contemplated which do not depart from the invention.

While the present invention has been described herein in terms of delivering an expandable stent to a desired location within a patient's blood vessel, the delivery catheter can also be employed to deliver stents to locations within other body lumens so that the stents can be expanded to maintain the patency of those body lumens. In addition, the detachable sheath may be used to secure self-expanding stents to delivery catheters prior to deployment.

Thus, the detachable sheath of the present invention provides an improved stent delivery catheter assembly having an efficient means to removably secure a stent onto an expandable member for delivery and insertion into a patient's vasculature. The detachable sheath adequately covers the stent and the catheter's expandable member during traverse of the patient's vasculature, while adding little or no additional outer diameter profile to the catheter assembly. The sheath prevents the stent and stent edges from catching on the vasculature or previously deployed stent as the catheter assembly traverses the patient's anatomy. Similarly, the detachable sheath aids in retaining the stent while advancing through difficult lesions, without unduly decreasing the flexibility and steerability of the catheter assembly, or otherwise compromising the deliverability of the stent. The detachable sheath can be integrated into current stent delivery platforms and can be E-beam sterilized. Thus, a long felt

need in the industry has been solved by the catheter assembly having a detachable sheath as disclosed herein.

It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A catheter assembly for delivering an endoprosthesis within a body lumen, comprising:

a catheter having a proximal end portion and a distal end portion;

an expandable member associated with the distal end portion of the catheter;

an endoprosthesis disposed on the expandable member; and

a sheath disposed on the catheter and over the endoprosthesis, wherein the sheath is configured to rupture during expansion of the expandable member.

2. The catheter assembly of claim 1, wherein:

the sheath includes a weakened section configured to rupture during expansion of the expandable member.

3. The catheter assembly of claim 1, wherein:

the sheath includes a plurality of circumferential perforations.

4. The catheter assembly of claim 1, wherein:

the sheath is stretched over and secured to the expandable member.

5. The catheter assembly of claim 1, wherein:

the sheath is stretched over and secured to the distal end portion of the catheter.

6. The catheter assembly of claim 1, wherein:

the sheath has a proximal end secured to the proximal end portion of the catheter, and the sheath has a distal end removably secured to the distal end portion of the catheter.

7. The catheter assembly of claim 6, wherein:

the sheath is stretched prior to securing the sheath to the catheter.

8. The catheter assembly of claim 1, wherein:

the expandable member includes an inflatable dilatation balloon.

9. The catheter assembly of claim 1, wherein:

the endoprosthesis is a stent.

10. The catheter assembly of claim 9, wherein:

the stent is self-expanding.

11. The catheter assembly of claim 1, wherein:

the catheter includes an over-the-wire intravascular catheter.

12. The catheter assembly of claim 1, wherein:
the catheter includes a rapid-exchange intravascular catheter.

13. The catheter assembly of claim 1, wherein:
the sheath is formed from an elastomeric material.

14. The catheter assembly of claim 1, wherein:
the sheath is formed from ESTANE with a shore hardness of 45D or lower.

15. The catheter assembly of claim 1, wherein:
the sheath is formed from a biodegradable material.

16. The catheter assembly of claim 1, wherein:
the sheath is formed from a material selected from the group consisting of polyurethanes, polyetheretherketone, polyether amides, copolyesters, and expandable polytetrafluoroethylene.

17. The catheter assembly of claim 1, wherein:
the sheath is formed from a material selected from the group consisting of polyethylenes, polyamides, polyesters, polyether amides, polyurethane, copolyesters, and polytetrafluoroethylene.

18. An apparatus for delivering an endoprosthesis within a body lumen, comprising:

an endoprosthesis;

means for delivering the endoprosthesis within a body lumen, the means for delivering having a proximal end portion and a distal end portion;

means for expanding the endoprosthesis, the means for expanding associated with the distal end portion of the means for delivering, wherein the endoprosthesis is disposed on the means for expanding; and

means for retaining the endoprosthesis, the means for retaining being disposed on the means for delivering and over the endoprosthesis, wherein the means for retaining is configured to detach from the means for delivering when inflation fluid is introduced into the means for expanding.

19. The apparatus of claim 18, wherein:

the means for retaining includes a weakened section configured to rupture during expansion of the means for expanding.

20. The apparatus of claim 18, wherein:

the means for retaining includes a plurality of circumferential perforations.

21. The apparatus of claim 18, wherein:

the means for retaining is stretched over and secured to the means for expanding.

22. The apparatus of claim 18, wherein:

the means for retaining is stretched over and secured to the distal end portion of the means for delivering.

23. The apparatus of claim 18, wherein:

the means for retaining has a proximal end secured to the proximal end portion of the means for delivering, and the means for retaining has a distal end secured to the distal end portion of the means for delivering.

24. The apparatus of claim 23, wherein:

the means for retaining is stretched prior to securing the means for retaining to the means for delivering.

25. The apparatus of claim 18, wherein:

the means for expanding includes an inflatable dilatation balloon.

26. The apparatus of claim 18, wherein:

the endoprosthesis is a stent.

27. The apparatus of claim 18, wherein:
the stent is self-expanding.

28. The apparatus of claim 18, wherein:
the means for delivering includes an over-the-wire intravascular catheter.

29. The apparatus of claim 18, wherein:
the means for delivering includes a rapid-exchange intravascular catheter.

30. The apparatus of claim 18, wherein:
the means for retaining is formed from an elastomeric material.

31. The apparatus of claim 18, wherein:
the means for retaining is formed from ESTANE.

32. The apparatus of claim 18, wherein:
the means for retaining is formed from a biodegradable material.

33. The apparatus of claim 18, wherein:

the means for retaining is formed from a material selected from the group consisting of polyurethanes, polyetheretherketone, polyether amides, polyurethane, copolyesters, and expandable polytetrafluoroethylene.

34. The apparatus of claim 18, wherein:

the means for retaining is formed from a material selected from the group consisting of polyethylenes, polyamides, polyesters, polyether amides, polyurethane, copolyesters, and polytetrafluoroethylene.

35. A catheter assembly for delivering a stent within a patient's vasculature, comprising:

a catheter tube having a proximal end portion and a distal end portion;

a balloon formed on the distal end portion of the catheter tube;

a stent disposed on the balloon; and

a sheath secured to the distal end portion of the catheter tube, wherein the sheath is stretched over the balloon and over the stent, and wherein the sheath includes a weakened section configured to rupture during inflation of the balloon.

36. The catheter assembly of claim 35, wherein:

the weakened section comprises a plurality of circumferential perforations.

37. The catheter assembly of claim 36, further comprising:

a guidewire and an elongate tubular member having a proximal end portion and a distal end portion, the guidewire being slidably disposed within a lumen of the elongate tubular member, the elongate tubular member being disposed within the catheter tube, and the distal end portion of the catheter tube being secured to the distal end portion of the elongate tubular member.

38. The catheter assembly of claim 35, wherein:

the catheter assembly is configured as an over-the-wire intravascular catheter assembly.

39. The catheter assembly of claim 35, wherein:

the catheter assembly is configured as a rapid-exchange intravascular catheter assembly.

40. The catheter assembly of claim 35, wherein:

the sheath is formed from an elastomeric material.

41. The catheter assembly of claim 35, wherein:

the sheath is formed from ESTANE.

42. The catheter assembly of claim 35, wherein:

the sheath is formed from a biodegradable material.

43. The catheter assembly of claim 35, wherein:

the sheath is formed from a material selected from the group consisting of polyurethanes, polyetheretherketone, polyether amides, copolyesters, and expandable polytetrafluoroethylene.

44. The catheter assembly of claim 35, wherein:

the sheath is formed from a material selected from the group consisting of polyethylenes, polyamides, polyesters and polytetrafluoroethylene.

45. A catheter assembly for delivering a stent within a patient's vasculature, comprising:

a catheter tube having a proximal end portion and a distal end portion;

a balloon formed on the distal end portion of the catheter tube;

a stent disposed on the balloon; and

a sheath having a proximal end portion positioned proximate the proximal end portion of the catheter tube, the sheath further having a distal end portion configured with a weakened section, the distal end portion of the sheath being secured to the distal end portion of the catheter tube.

46. The catheter assembly of claim 45, further comprising:

an inflation port positioned proximate the proximal end portion of the sheath and in fluid communication with the sheath, the proximal end portion of

the sheath being secured to the proximal end portion of the catheter tube, wherein the sheath is stretched prior to securing the sheath to the catheter tube.

47. The catheter assembly of claim 46, wherein:
the weakened section comprises a plurality of perforations.

48. The catheter assembly of claim 47, further comprising:
a guidewire and an elongate tubular member having a proximal end portion and a distal end portion, the guidewire being slidably disposed within a lumen of the elongate tubular member, the elongate tubular member being disposed within the catheter tube, and the distal end portion of the catheter tube being secured to the distal end portion of the elongate tubular member.

49. The catheter assembly of claim 45, wherein:
the catheter assembly is configured as an over-the-wire intravascular catheter assembly.

50. The catheter assembly of claim 45, wherein:
the catheter assembly is configured as a rapid-exchange intravascular catheter assembly.

51. The catheter assembly of claim 45, wherein:
the sheath is formed from an elastomeric material.

52. The catheter assembly of claim 45, wherein:
the sheath is formed from ESTANE.

53. The catheter assembly of claim 45, wherein:
the sheath is formed from a biodegradable material.

54. The catheter assembly of claim 45, wherein:
the sheath is formed from a material selected from the group consisting of polyurethanes, polyetheretherketone, polyether amides, copolyesters, and expandable polytetrafluoroethylene.

55. The catheter assembly of claim 45, wherein:
the sheath is formed from a material selected from the group consisting of polyethylenes, polyamides, polyesters, polyether amides, copolyesters, and polytetrafluoroethylene.

56. A catheter assembly for delivering a self-expanding within a body lumen, comprising:
a catheter having a proximal end portion and a distal end portion;
an expandable member associated with the distal end portion of the catheter; and

a sheath disposed on the catheter and adapted to extend over the self-expanding stent when the self-expanding stent is in its collapsed position, wherein the sheath is configured to rupture during expansion of the expandable member.

57. The catheter assembly of claim 56, wherein:

the sheath includes a weakened section configured to rupture during expansion of the expandable member.

58. The catheter assembly of claim 56, wherein:

the sheath includes a plurality of circumferential perforations.

59. The catheter assembly of claim 56, wherein:

the sheath is stretched over and secured to the expandable member.

60. The catheter assembly of claim 56, wherein:

the sheath is stretched over and secured to the distal end portion of the catheter.

61. The catheter assembly of claim 56, wherein:

the sheath is stretched prior to securing the sheath to the catheter over the self-expanding stent.

62. A method of delivering an endoprosthesis into a desired location within a body lumen, the method comprising:

providing a catheter assembly including a catheter having a proximal end portion and a distal end portion, an expandable member associated with the distal end portion of the catheter, an endoprosthesis disposed on the expandable member, and a sheath disposed on the catheter and over the endoprosthesis, wherein the sheath is configured to rupture during expansion of the expandable member;

advancing the distal end portion of the catheter, the sheath, the expandable member and the endoprosthesis though the body lumen to a desired location;

expanding the expandable member so as to rupture the sheath;

further expanding the expandable member so as to expand the endoprosthesis at the desired location;

contracting the expandable member; and

withdrawing the catheter, the expandable member, and the sheath from the body lumen.

63. A method of delivering a stent into a desired location within a patient's vasculature, the method comprising:

providing a catheter assembly including a catheter tube having a proximal end portion and a distal end portion, a balloon formed on the distal end portion of the catheter tube, a stent disposed on the balloon, and a sheath secured to the distal end portion of the catheter tube, wherein the sheath is stretched over the balloon and over the stent, and wherein the sheath includes a weakened section configured to rupture during inflation of the balloon;

advancing the distal end portion of the catheter tube, the sheath, the balloon and the stent though the vasculature to a desired location;

inflating the balloon to a first pressure so as to rupture the sheath;

further inflating the balloon so as to expand the stent into the desired location;

deflating the balloon; and

withdrawing the catheter tube, the balloon and the sheath from the vasculature.

64. A method of delivering a stent into a desired location within a patient's vasculature, the method comprising:

providing a catheter assembly including a catheter tube having a proximal end portion and a distal end portion, a balloon formed on the distal end portion of the catheter tube, a stent disposed on the balloon, a sheath having a proximal end portion secured to the proximal end portion of the catheter tube, the sheath further having a distal end portion configured with a weakened section, the distal end portion of the sheath being secured to the distal end portion of the catheter tube such that the sheath is stretched prior to securing the sheath to the catheter tube, and an inflation port positioned proximate the proximal end portion of the sheath and in fluid communication with the sheath;

advancing the distal end portion of the catheter tube, the distal end portion of the sheath, the balloon and the stent though the vasculature to a desired location;

inflating the sheath so as to disengage the sheath from the distal portion of the catheter tube;

inflating the balloon so as to expand the stent into the desired location;

deflating the balloon; and

withdrawing the catheter tube, the balloon and the sheath from the vasculature.

ABSTRACT

A catheter assembly for delivering an endoprosthesis within a body lumen. A delivery catheter assembly is provided which includes a detachable sheath for removably securing an endoprosthesis, for example a stent, onto an expandable member, for example, a dilatation balloon. The detachable sheath is associated with the distal end portion of the catheter assembly having an expandable member therein, whereby inflation of the expandable member ruptures the detachable sheath, thereby exposing the stent for implantation into a body lumen. Alternatively, the detachable sheath may be inflated separately from the expandable member, and/or may be manually retracted from the stent. The detachable sheath prevents movement of the stent relative to the catheter assembly during deployment in a body lumen, such as a patient's vasculature, by covering the stent until the stent is positioned at a desired location within the body lumen. The catheter assembly is inserted into the vasculature and manipulated so that the stent is positioned proximate a desired location in the vasculature, such as at a lesion or stenosis in a coronary artery. The detachable sheath protects the stent and the expandable member while traversing the vasculature, and the sheath automatically retracts or is manually retracted prior to implanting the stent.

FIG. 1

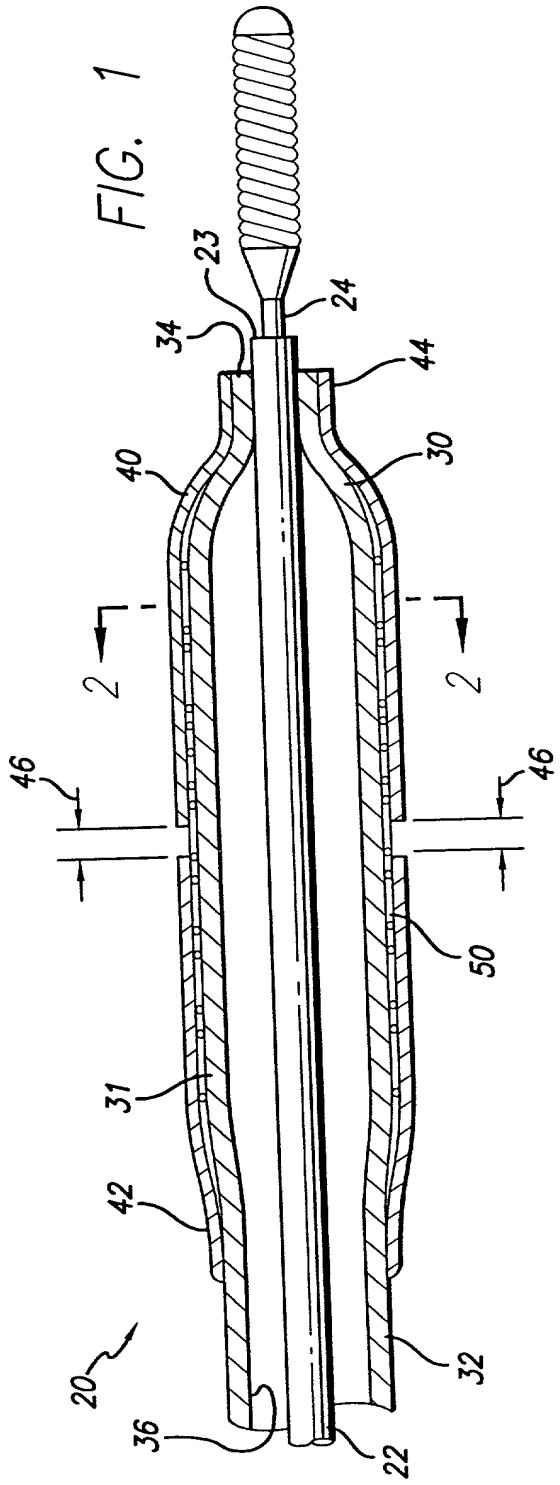

FIG. 2

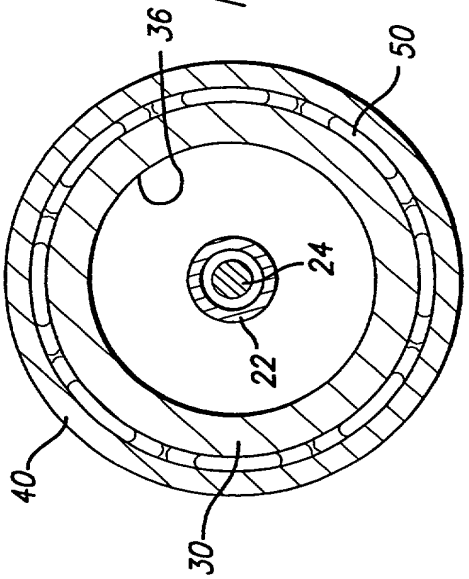

FIG. 3

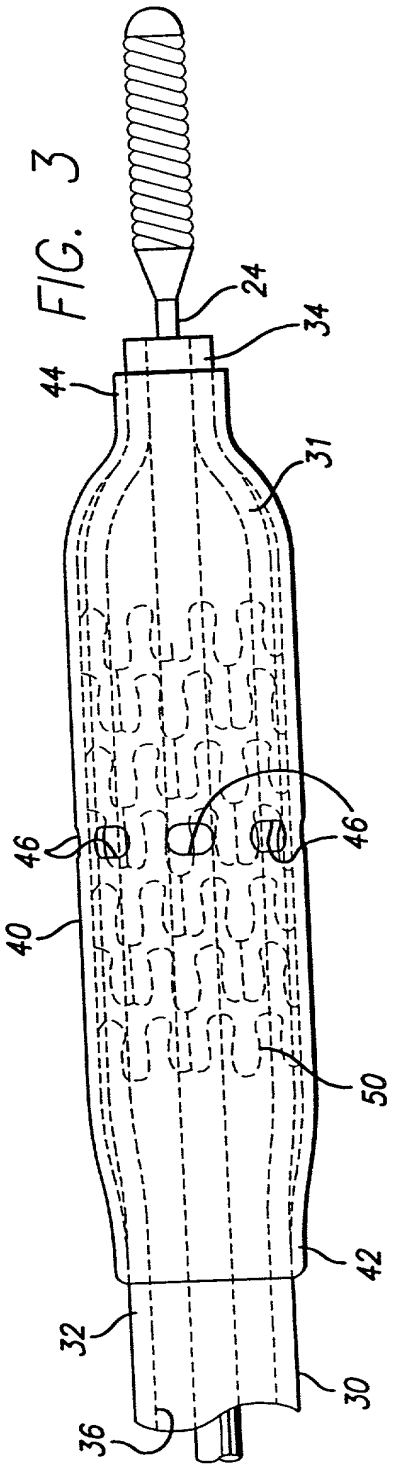
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FIG. 4

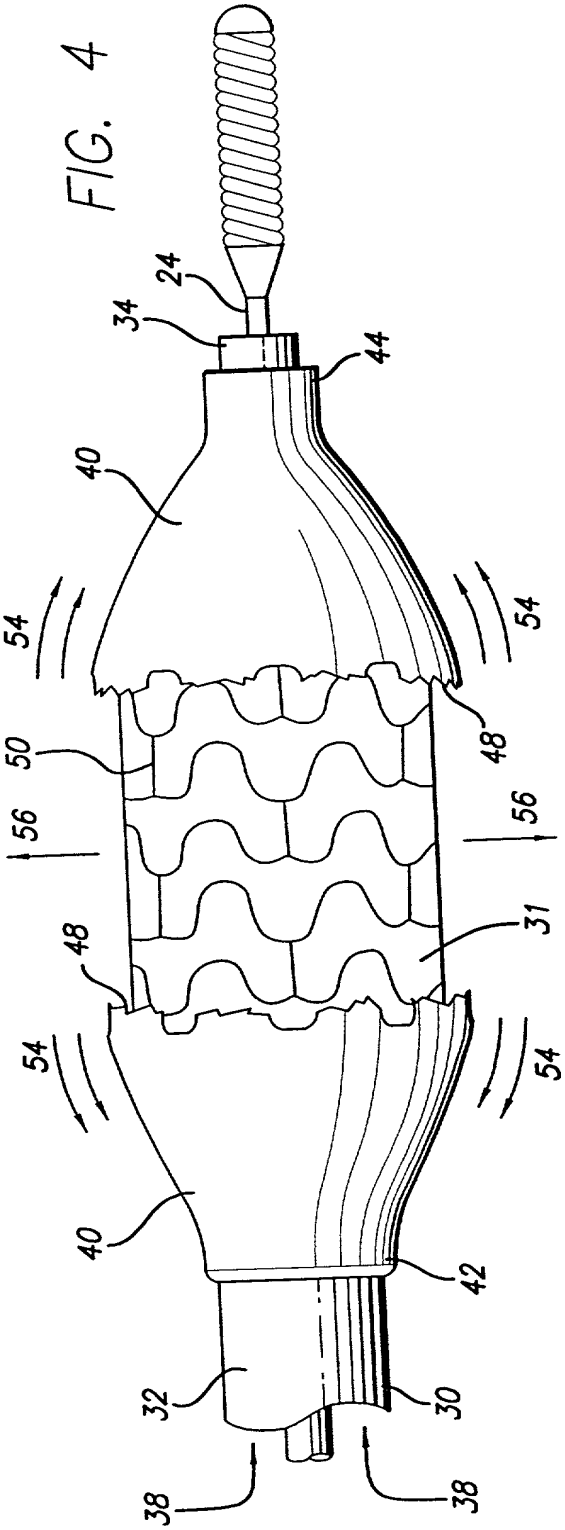
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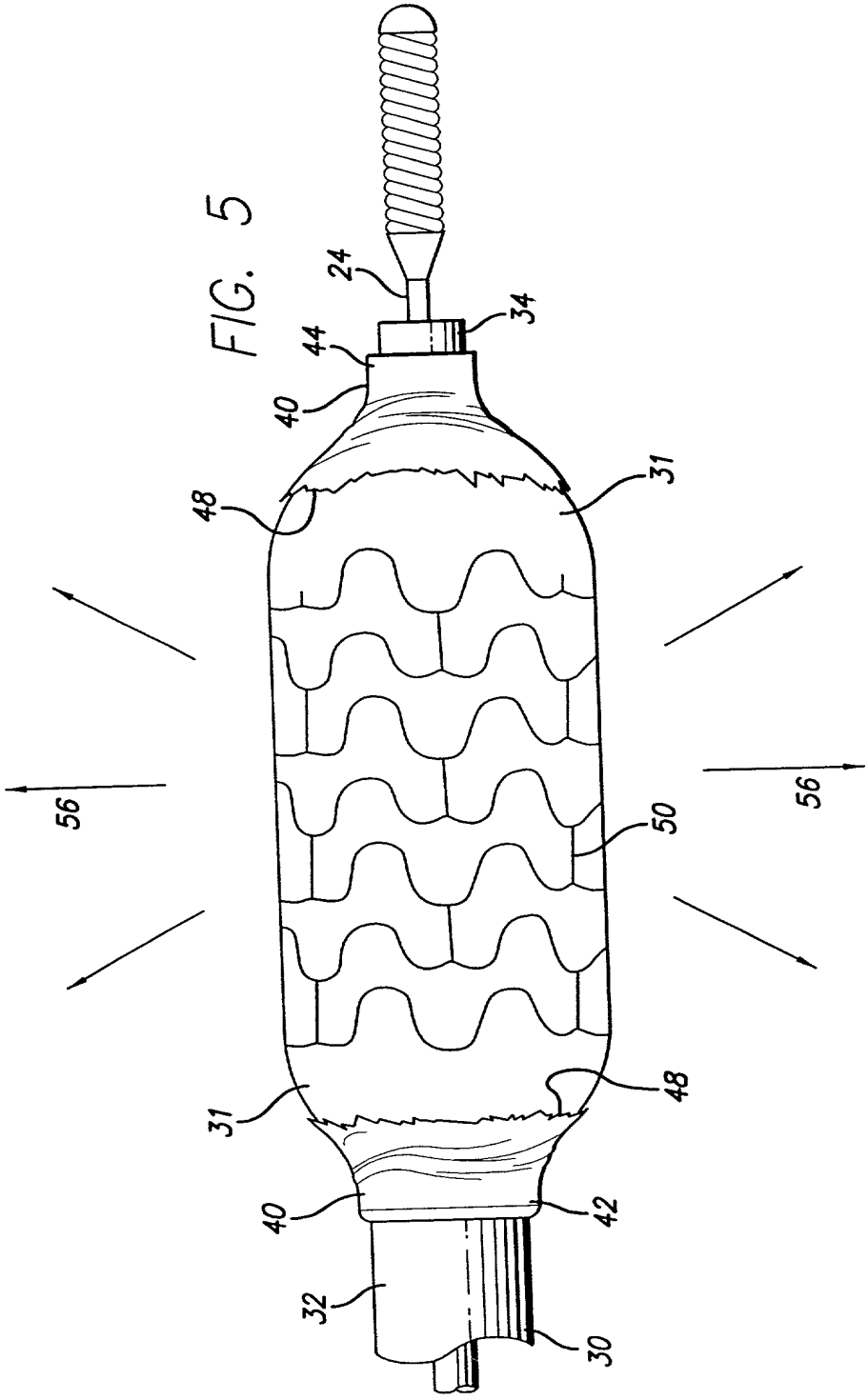
FIG. 5



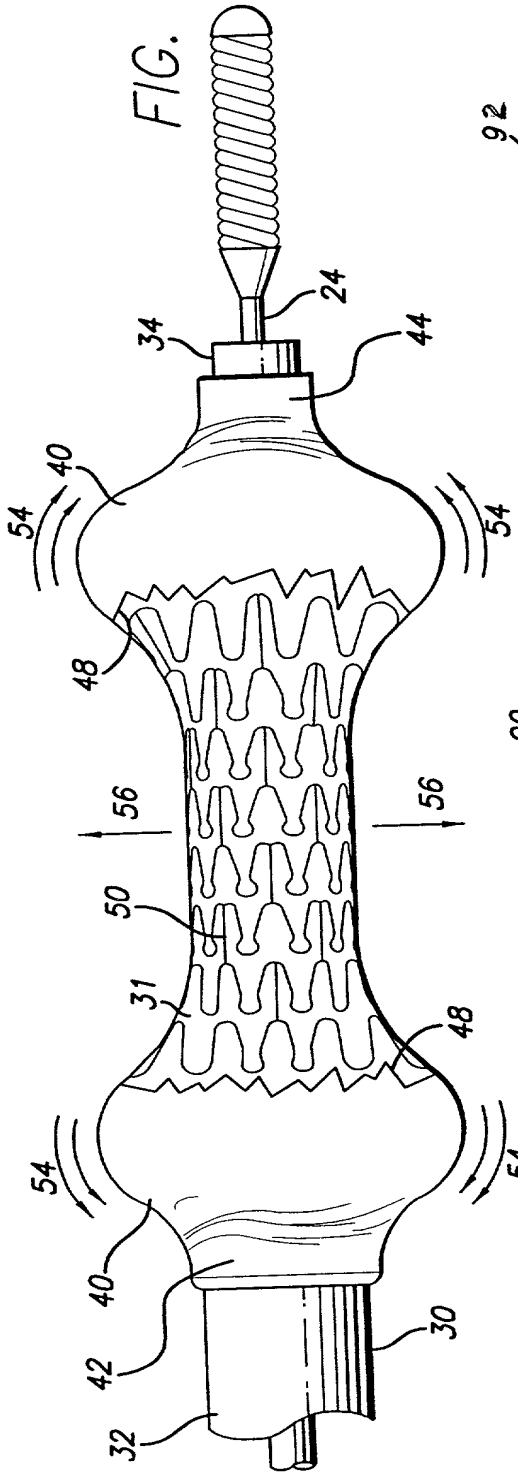


FIG. 6

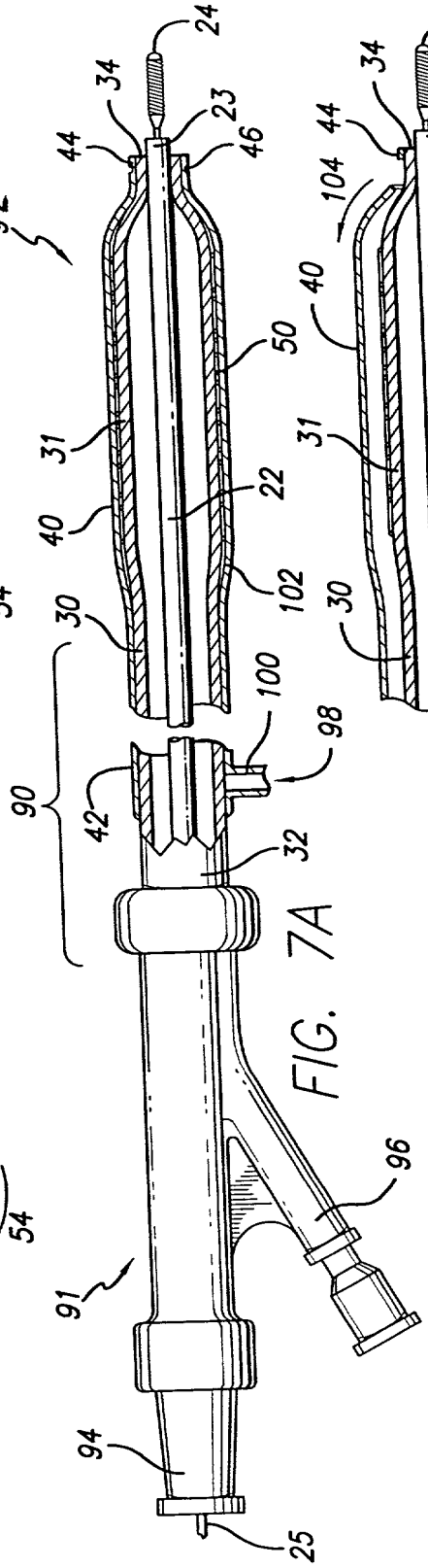


FIG. 7A

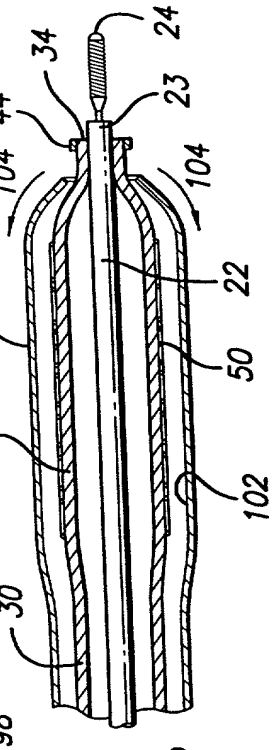


FIG. 7B

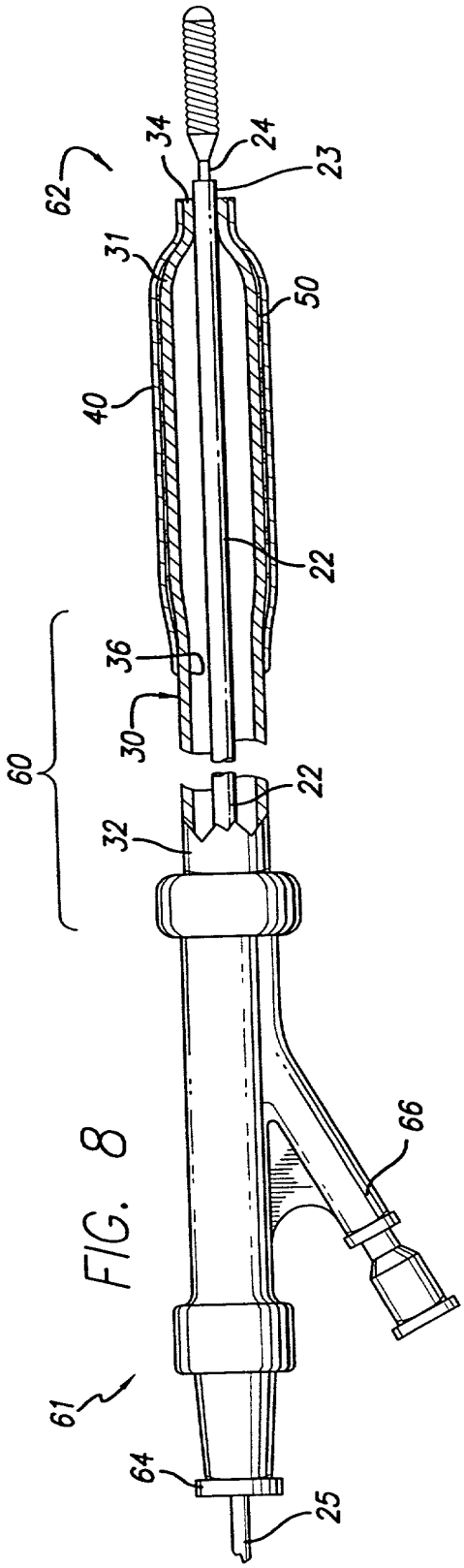

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FIG. 8

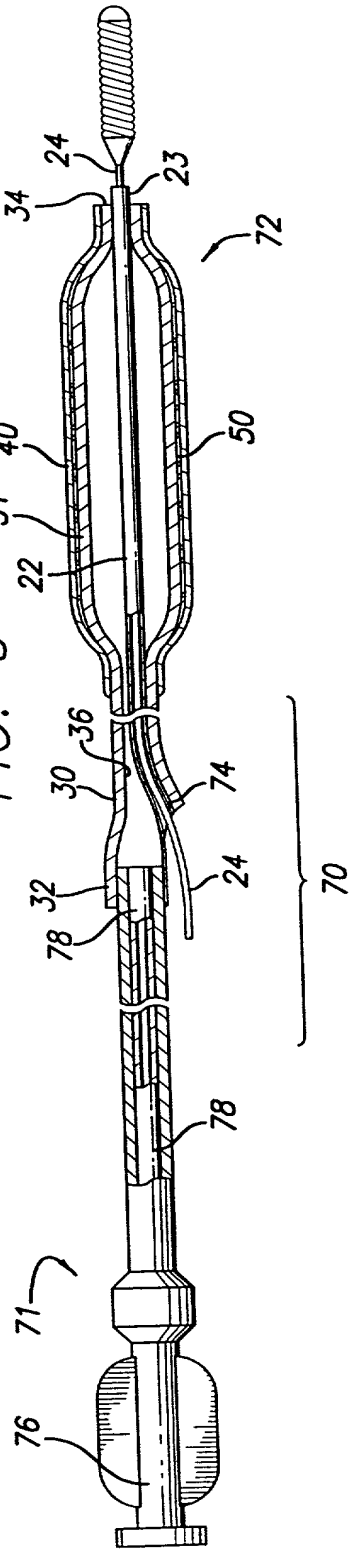
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FIG. 9

FIG. 10

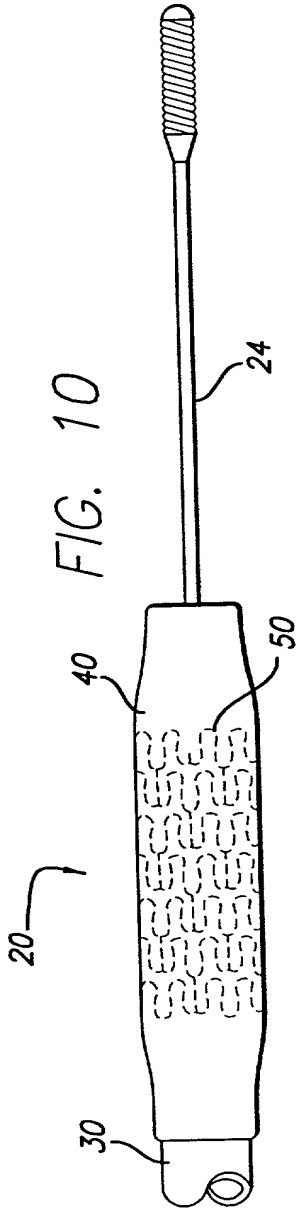
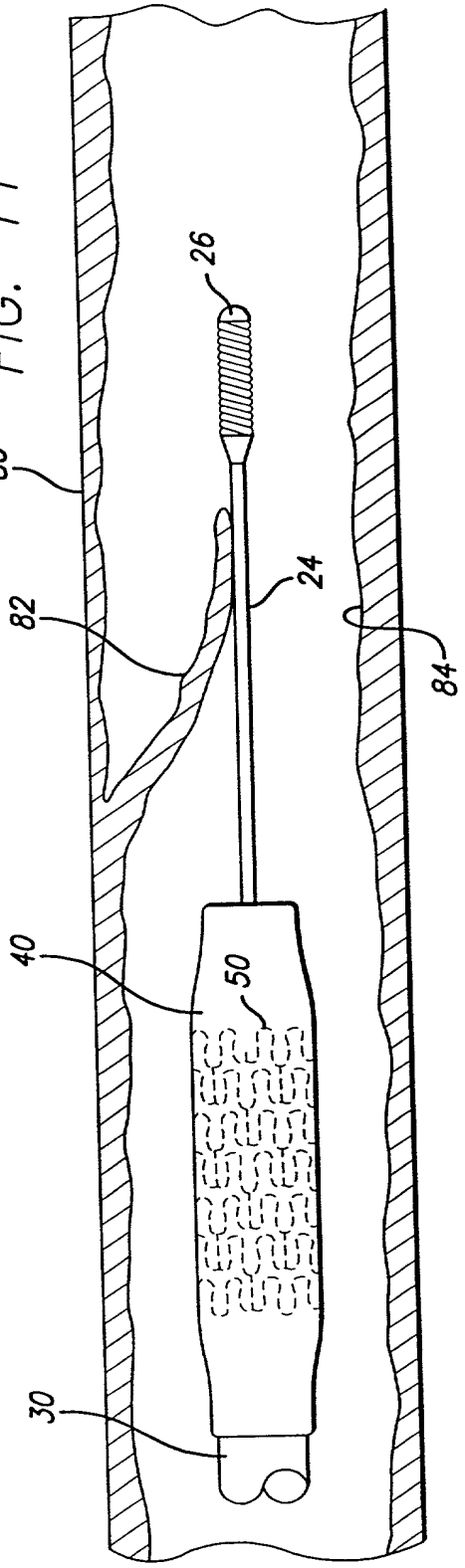


FIG. 11



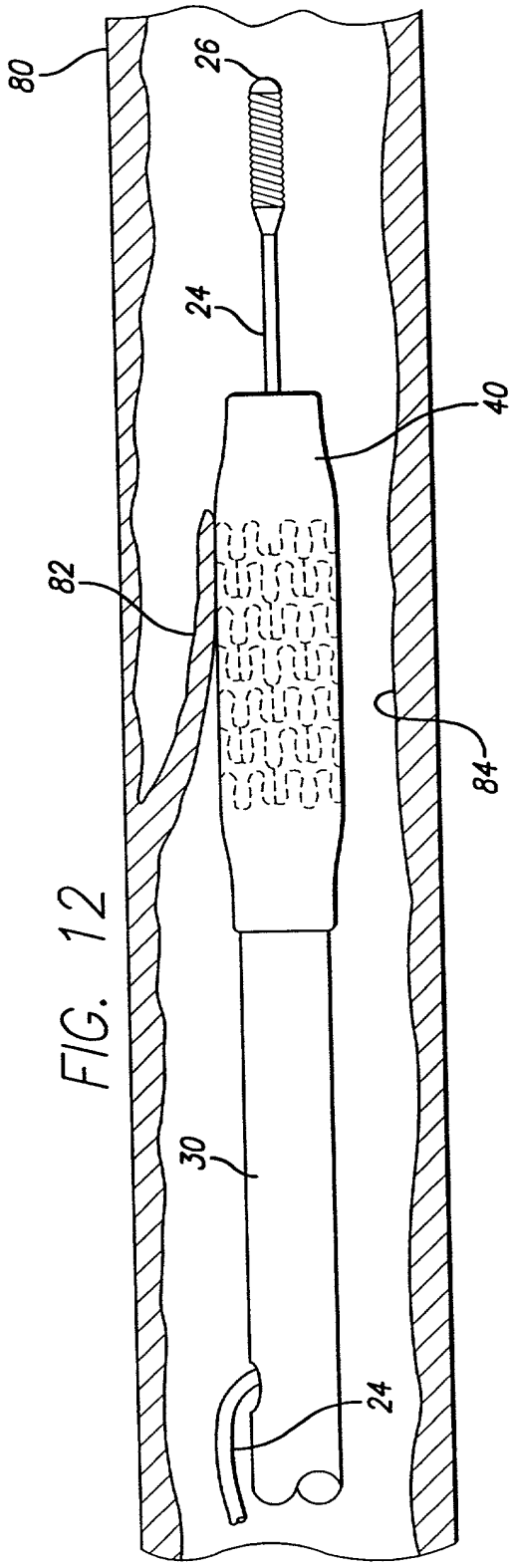


FIG. 12

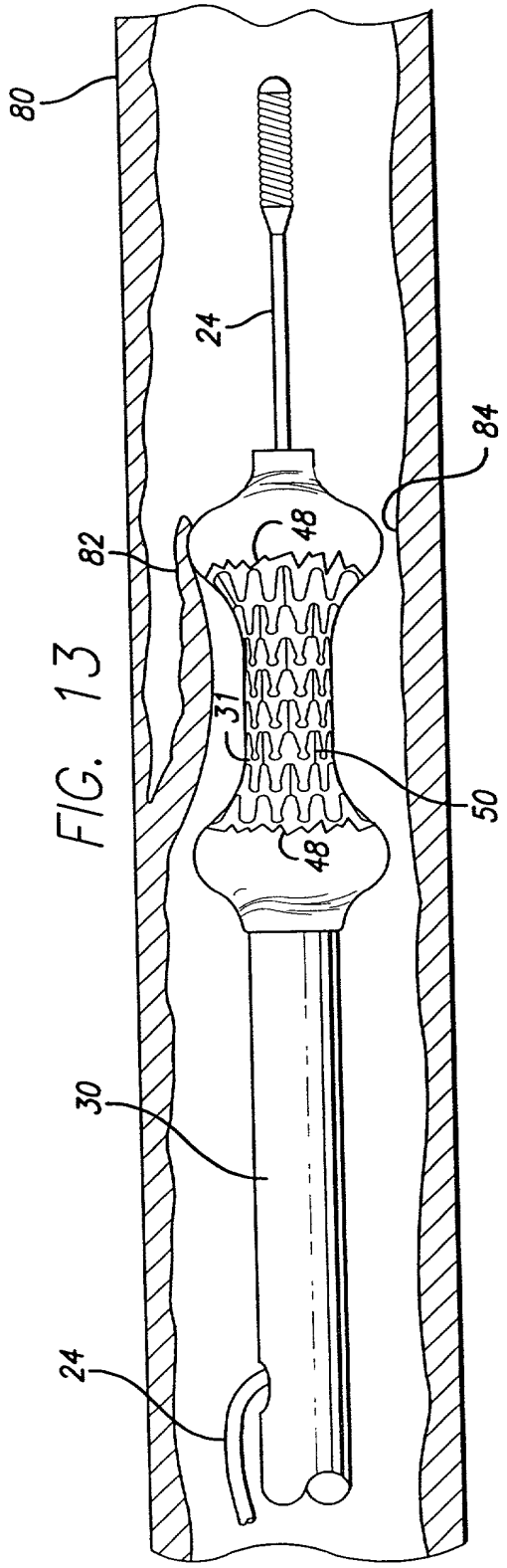


FIG. 13

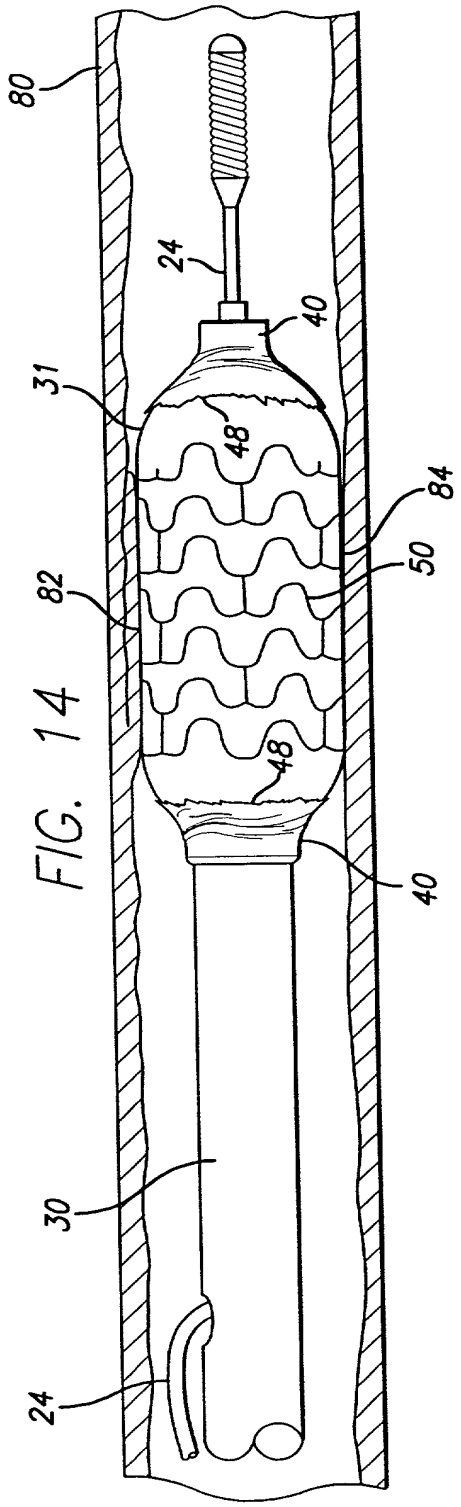


FIG. 14

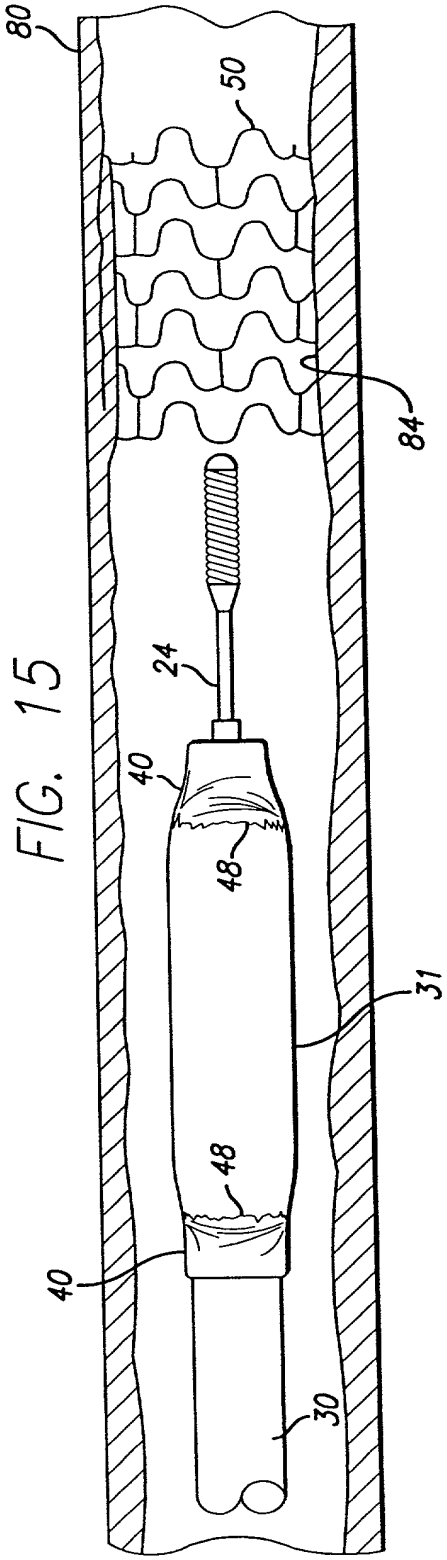


FIG. 15

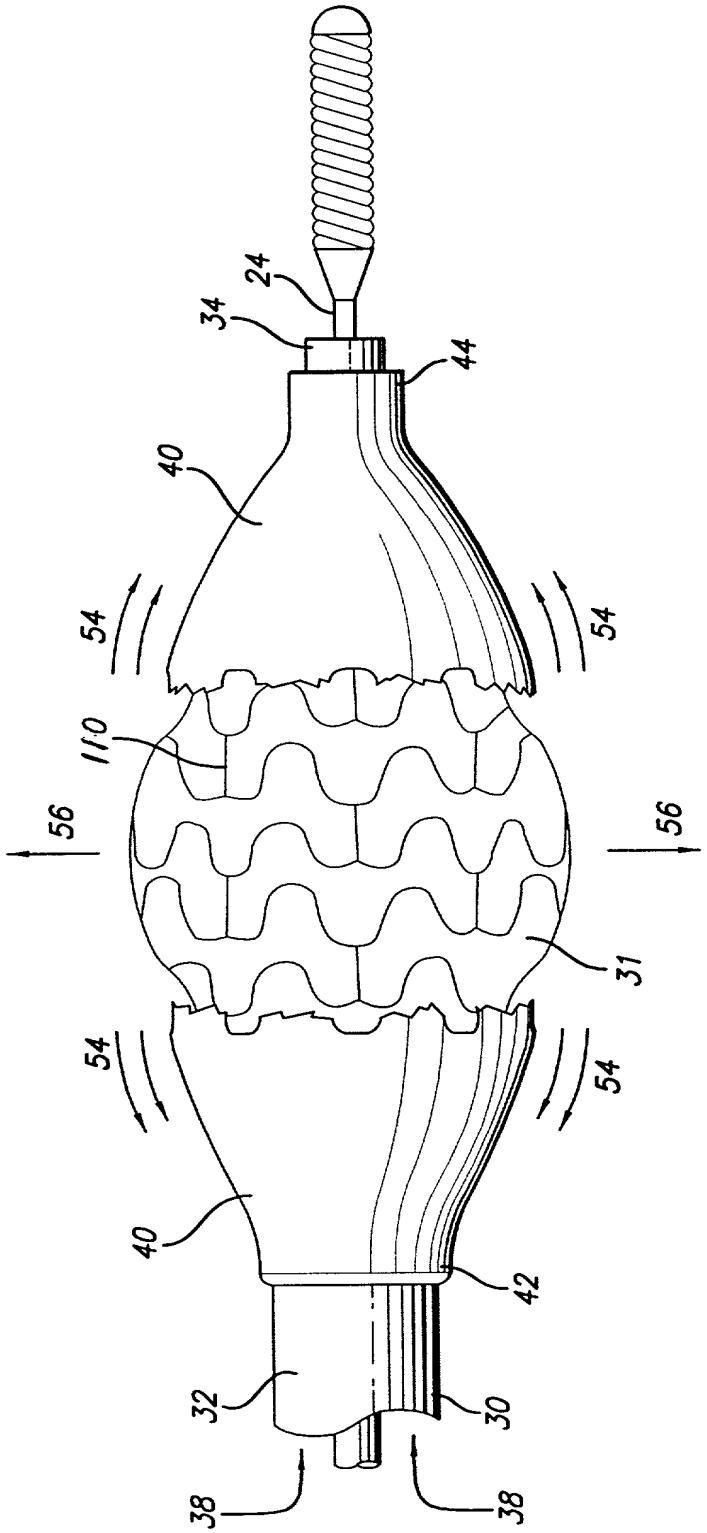


FIG. 16

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As the below named inventors, we hereby declare that:

Our residences, post office addresses and citizenship are as stated below next to our names, Brent Belding, Brian P. Cahill, Jeffrey T. Ellis, Richard J. Foust, Arkady Kokish, Florencia Lim and Chi Long.

We believe we are original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled DETACHABLE SHEATH TO PROVIDE PRE-DEPLOYMENT STENT SECURITY AND ENHANCED DELIVERY PRECISION, the specification of which (check one)

_X_ is attached hereto

___ was filed on _______________

Application Serial No. ____________

and was amended on (or amended through) ________

(if applicable)

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above.

We acknowledge the duty to disclose information which is material patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119 (a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
Number	Country	Day/Month/Year filed	Yes	No
None				

We hereby claim the benefit under Title 35, United States Code, Sec. 119(e) of any United States provisional application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Sec. 112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Sec. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Appln. Serial No.	Filing Date	Status (patented, pending, abandoned)
None		

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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BSB
7/28/2000

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Inventor's signature: Brian P Cahill

Date: 7/31, 2000

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Date: 7/28, 2000

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Inventor's signature: _____

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Inventor's signature: Florencia Lim

Date: 7/28, 2000

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Inventor's signature: Chi Long

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Citizenship: USA

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